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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,390	09/27/2001	Lei Zhang	GENE1400-2	7376

35938 7590 09/09/2004

BIOTECHNOLOGY LAW GROUP
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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/966,390

Applicant(s)

ZHANG ET AL.

Examiner

Mark W Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-89,91-103,106-109 and 111-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-89,91-103,106-109 and 111-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 81-82, 84-85, 87-89, 96-98, 100, 102, 103, 114-117 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann USPN 5,464,386. Hofmann teaches an electroporation device with an electrode member 22 having a meandering electrode array configuration attached to a support member 26 by a pinned (28) bracket that allows rotation and conformation to the body part. A pulse generator 12 is connected to the support member as well as a source of drug to be infused. The electrode is coated on a thin film 22 and are separated by applicant's claim distance (column 3 lines 60-68). Everything about the Hofman device is disposable since anything may be disposed of including Hofman's electrodes. At least a portion of the support member must be conductive to transmit the pulses from the generator the electrode head including wires and contacts. The electrode is insulated by member and 22 and may be considered porous if the reservoir 20 (column 3 lines 60-63) or the thin film is considered to be part of the electrode.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 83, 86, 91-95, 99, 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 5464386. While Hofmann is silent whether his electrodes are detachable or not, the examiner believes with the proper tools the Hofmann pins may be displace and the electrode removed. It is obvious to provide such a pin mounting and nothing in the disclosure would indicate that the electrode is to remained fixed. In addition, it is well know in the art to reuse electrodes on electroporation and iontophoretic support members so that the devices may be used with different drugs for different people. As shown in figure 2, pin 28 enters a tubular portion of the electrode member 16 to pin the electrode thereon. The examiner also considers the widening of the electrodes and the inclusion of back up power source would have been obvious since many tools and instruments are made in such a fashion.

Claims 106-107, 111-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 5,464,386 in view of Eppstein USPN 5,445,611. To have include and iontophoresis and/o ultrasound member in the unit to enhance delivery as taught by Eppstein would have been obvious.

Claim 109 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann USPN 5,464,386 in view of Weaver et al USPN 5,019,034. To have included a skin resistance monitoring unit in the Hofmann device to monitor skin breakdown would have been obvious in view of Weaver et al (claim 19) .

Claims 81 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al USPN 6,283,951 in view of Crandell et al USPN 5,304,120. Flaherty

et al teaches a probe support member that may include an electrode for effecting electroporation (column 11 lines 16-29). The probe may also house a pressure sensor (column 17 lines 42-53). Applicant differs in reciting at least one pair of electrodes which is consider to be obvious in view of the teachings of Crandell et al. Generally two electrodes or an array is necessary to localize the electroporation members.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

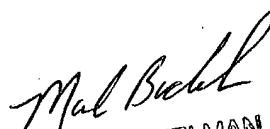
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

September 7, 2004


MARK BOCKELMAN
PRIMARY EXAMINER